ASX Announcement

31 October 2022

Quarterly Activities & Cash Flow Report

Quarter ended 30 September 2022

Sydney, Australia – 31 October 2022: OncoSil Medical Ltd (ASX: OSL) (**OncoSil** or the **Company**), is pleased to provide an update on activities, for the quarter ending 30 September 2022. OncoSil is a medical device company that is commercialising its platform technology for the treatment of patients with locally advanced pancreatic cancer (LAPC) and seeking FDA approval for the OncoSil™ device to treat patients with bile duct cancer or distal cholangiocarcinoma (DCC).

Key Highlights

- ✓ **Bupa UK Approves Reimbursement for OncoSil in the UK at The London Clinic:** the first health insurance company to provide reimbursement for the breakthrough OncoSil™ device in the private payer market in the UK;
- ✓ **Second Patient commercially treated in Spain successfully resected:** Another important achievement, given the OncoSil™ device is normally administered only to unresectable patients suffering LAPC;
- ✓ **Expansion of sites to 4 hospitals in Spain now using the OncoSil™ device;**
- ✓ **Mr Brian Leedman appointed to the OncoSil Board:** Further board renewal;
- ✓ **USA HDE for distal cholangiocarcinoma:** Currently in ongoing discussions with FDA; and
- ✓ **Cash position:** Cash balance of $7.95 million as at 30 September 2022.

All financial results in the attached 4C are in Australian dollars and are unaudited.

European Union and the United Kingdom

The team have continued to concentrate on assisting with local regulatory and ethics approvals for the OSPREY patient registry.

The Company has continued to work on several initiatives in preparation for market access, health insurance coverage and reimbursement applications in major European markets.

Health Insurance reimbursement for OncoSil in the UK at The London Clinic

In July 2022, Bupa UK Insurance became the first health insurance company to provide reimbursement for the breakthrough OncoSil™ device in the private payer market in the UK.

The London Clinic worked with OncoSil to obtain this approval to cover Bupa UK's health insurance customers for implantation of the OncoSil™ device in the treatment of LAPC.

In August 2022, an additional leading health insurance company also agreed to provide reimbursement at The London Clinic.

The OncoSil team will be working with other insurers to expand reimbursement for patient access to treatments at The London Clinic and other private institutions in the United Kingdom.

Patient treated with the OncoSil™ Device in Spain proceeded to success resection of the tumour in the pancreas

In July 2022, the second patient treated at The Hospital Universitario de Fuenlabrada in Madrid, Spain has undergone a successful resection of the LAPC tumour. In the PanCO trial, 23.8% of patients who were treated with the OncoSil™ device were successfully resected which has been demonstrated to improve patient outcomes from this insidious disease. OncoSil is continuing to work with additional institutions in Spain and throughout Europe, to accelerate the use of the OncoSil™ device for the benefit of patients suffering from LAPC.

Expansion of sites in Spain using the OncoSil™ device

During the quarter, the team has expanded the number of hospital sites who are trained in implanting the OncoSil™ device. Subsequent to the quarter, the fourth hospital site in Spain has implanted the OncoSil™ device.

The successful resection of the patient at The Hospital Universitario de Fuenlabrada in Madrid has generated increased interest from Key Opinion Leaders in Spain and elsewhere throughout Europe.

Mr Brian Leedman appointed to the Board of OncoSil

In September 2022, Mr Brian Leedman was appointed to the Board as a Non-Executive Director. Mr Leedman is a marketing and investor relations professional with over 15 years' experience in the biotechnology industry. Mr Leedman is the founder of ResApp Diagnostics Pty Ltd which was acquired by Narhex Life Sciences Limited to form ResApp Health Limited where Mr Leedman is the Executive Director of Corporate Affairs. ResApp Health was acquired by Pfizer (Aust) Limited under a scheme of arrangement.

Mr Leedman is an experienced public company director having formerly been the Chairman of Neurotech International Limited, Nutritional Growth Solutions Limited, Neuroscientific Biopharmaceuticals Limited and was a Director of Alcidion Corporation Limited.

USA Humanitarian Device Exemption for distal cholangiocarcinoma

OncoSil continues to have an ongoing dialogue with the US Food and Drug Administration (FDA) in regard to its filed Humanitarian Device Exemption (HDE) application for its OncoSil™ device in the treatment of distal cholangiocarcinoma (DCC or bile duct cancer). A further meeting is scheduled early next year.

Corporate

As at 30 September 2022, OncoSil had a cash balance of $7.95 million. During the Quarter, the Company's net cash used in operations was $3.2 million, with $0.7 million invested in R&D activities. Item 6.1 of the Appendix 4C relates to director fees and salaries paid in the quarter.

Authorisation & Additional Information

This announcement was authorised by the Board of Directors of OncoSil Medical Limited.

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About OncoSil

OncoSil Medical is a medical device company seeking to advance radiation for cancer patients. OncoSil Medical's lead product, OncoSil™ is a targeted radioactive isotope (Phosphorus-32), implanted directly into a patient's pancreatic tumours via an endoscopic ultrasound.

Treatment with the OncoSil™ is intended to deliver more concentrated and localised beta radiation compared to external beam radiation. OncoSil Medical has conducted six clinical studies with positive results on tolerability, safety and efficacy. CE Marking has been granted for the OncoSil™ device which can be marketed in the European Union and the United Kingdom. The OncoSil™ device has also been classified a Breakthrough Device in the European Union and the United Kingdom.

An Investigational Device Exemption (IDE) has been granted by the United States Food and Drug Administration (FDA) to conduct a clinical study of the OncoSil™ device aimed at supporting a PMA approval.

In December 2018, the FDA granted Humanitarian Use Designation (HUD) for the OncoSil™ device for the treatment of unresectable bile duct cancer. In March 2020, the FDA granted Breakthrough Device Designation for the OncoSil™ for unresectable pancreatic cancer in conjunction with systemic chemotherapy.

Pancreatic cancer is typically diagnosed at a later stage, when there is a poor prognosis for long-term survival. The World Cancer Research Fund estimated that in 2012, 338,000 people globally were diagnosed with pancreatic cancer. The prognosis for patients diagnosed with pancreatic cancer, regardless of stage, is generally poor; the relative five-year survival rate for all stages combined is approximately 5%. The estimated world-wide market opportunity for OncoSil™ in pancreatic cancer exceeds $3b.

Forward Looking Statements

This document contains certain forward-looking statements, relating to OncoSil's business, which can be identified by the use of forward-looking terminology such as "promising", "plans", "anticipated", "will", "project", "believe", "forecast", "expected", "estimated", "targeting", "aiming", "set to", "potential", "seeking to", "goal", "could provide", "intends", "is being developed", "could be", "on track", or similar expressions, or by express or implied discussions regarding potential filings or marketing approvals, or potential future sales of product candidates. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no assurance that any existing or future regulatory filings will satisfy the FDA and other authorities' requirements regarding any one or more product candidates, nor can there be any assurance that such product candidates will be approved by any authorities for sale in any market or that they will reach any particular level of sales. In particular, management's expectations regarding the approval and commercialisation of the product candidates could be affected by, among other things, unexpected trial results, including additional analysis of existing data, and new data; unexpected regulatory actions or delays, or government regulation generally; our ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry, and general public pricing pressures; and additional factors that involve significant risks and uncertainties about our products, product candidates, financial results and business prospects. Should one or more of these risks or uncertainties materialise, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected.

OncoSil Medical is providing this information as of the date of this document and does not assume any obligation to update any forward-looking statements contained in this document as a result of new information, future events or developments or otherwise.

Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity	
ONCOSIL MEDICAL LIMITED	
ABN	***Quarter ended ("current quarter")***
89 113 824 141	30 September 2022

	Consolidated statement of cash flows	**Current quarter $A'000**	**Year to date (3 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	133	133
1.2	Payments for		
	(a) research and development	(762)	(762)
	(b) product manufacturing and operating costs	(281)	(281)
	(c) advertising and marketing	(86)	(86)
	(d) leased assets	-	-
	(e) staff costs	(1,316)	(1,316)
	(f) administration and corporate costs	(849)	(849)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	-	-
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	-
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(3,161)**	**(3,161)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) entities	-	-
	(b) businesses	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 months) $A'000
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.2	Proceeds from disposal of:		
	(g) entities	-	-
	(h) businesses	-	-
	(i) property, plant and equipment	-	-
	(j) investments	-	-
	(k) intellectual property	-	-
	(l) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
2.6	**Net cash from / (used in) investing activities**	**-**	**-**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(161)	(161)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
3.10	**Net cash from / (used in) financing activities**	**(161)**	**(161)**

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 months) $A'000
4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	11,280	11,280
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,161)	(3,161)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(161)	(161)
4.5	Effect of movement in exchange rates on cash held	(5)	(5)
4.6	**Cash and cash equivalents at end of period**	**7,953**	**7,953**

5.	***Reconciliation of cash and cash equivalents*** *at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts*	**Current quarter $A'000**	**Previous quarter $A'000**
5.1	Bank balances	7,953	11,280
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**7,953**	**11,280**

6.	***Payments to related parties of the entity and their associates***	**Current quarter $A'000**
6.1	Aggregate amount of payments to related parties and their associates included in item 1	65
6.2	Aggregate amount of payments to related parties and their associates included in item 2	

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.

7.	***Financing facilities*** *Note: the term "facility' includes all forms of financing arrangements available to the entity.* *Add notes as necessary for an understanding of the sources of finance available to the entity.*	**Total facility amount at quarter end $A'000**	**Amount drawn at quarter end $A'000**
7.1	Loan facilities		
7.2	Credit standby arrangements		
7.3	Other (please specify)		
7.4	**Total financing facilities**		

7.5	**Unused financing facilities available at quarter end**	

7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.

8.	***Estimated cash available for future operating activities***	**$A'000**
8.1	Net cash from / (used in) operating activities (Item 1.9)	3,161
8.2	Cash and cash equivalents at quarter end (Item 4.6)	7,953
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	7,953
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	2.52
	Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.	

8.6 If Item 8.5 is less than 2 quarters, please provide answers to the following questions:

8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer:

8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer:

8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer:

Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

Compliance statement

1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.

2 This statement gives a true and fair view of the matters disclosed.

31/10/2022

Date: .....

By the Board

Authorised by: .....

(Name of body or officer authorising release – see note 4)

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.

2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.

3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.

4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [*name of board committee – e.g., Audit and Risk Committee*]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".

5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.